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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,204	11/08/2001	Mark Ashby	034298-124	3555

7590

11/25/2003

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EXAMINER

KENNEDY, SHARON E

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 11/25/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/007,204

Applicant(s)

Ashby

Examiner

Sharon Kennedy

Art Unit

3762



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 16, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 26-28 is/are pending in the application.
- 4a) Of the above, claim(s) 18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-12 is/are allowed.
- 6) ☒ Claim(s) 13, 15-17, and 26-28 is/are rejected.
- 7) ☒ Claim(s) 14 and 19 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Election/Restriction

2. Applicant's election with traverse of Group I, Species 1 (Figures 1, 2, 3a, 14 and 15) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the examiner has not set forth enough reasons for the election. This is not found persuasive because applicant merely sets forth legal arguments with spurious conclusory factual arguments that the species are not distinct. In addition, applicant has not admitted that the species are obvious variants as required in paragraph 9. Applicant should note that additional restriction requirements could have easily been made, for example, between claims positively reciting the hemostasis material and those not reciting such. Further, applicant is probably not aware that the examiner is accorded only 6.0 hours to do the entire first office action. This involves reading the application, analyzing the figures (22 sheets in the instant application), analyzing the claims, crafting a prior art search strategy, searching the claims, comparing the claims to the discovered prior art, deciding what claims are patentable, and preparing this office action. Accordingly, applicant's complaint that the restriction applied is unfair is not well-taken.

3. The requirement is still deemed proper and is therefore made FINAL.

4. Regarding the claims elected, applicant has not carefully considered the elected invention and set forth the proper claims for consideration. Claims 10 and 18 are directed to the bleed back tube 26 being on the hydration chamber, which is shown in figure 4. Clearly, this species is not

represented in the figures elected. Accordingly, claims 10 and 18 are withdrawn from consideration. Claims 5 and 6 are directed to a tapered hydration chamber, the tapered portion being able to compress the hemostasis material. These features are not shown in the elected figures. Accordingly, claims 5 and 6 are also withdrawn from consideration. (But see Allowable Subject Matter).

Drawings

5. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on June 9, 2003 have not been approved. See below.
6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the features of claims 5 and 6, wherein the hydration chamber has a tapered portion in between two larger portions, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Since this subject matter is described in the original disclosure, applicant may submit drawings showing this feature.
7. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There does not appear to be a description of claims 5 and 6 in the specification or the drawings. However, since this subject matter was described in the original claims, applicant should submit an amendment to the specification and additional drawings. See also the comments above regarding the objection to the drawings.

Claim Rejections - 35 USC § 112

9. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 is dependent on claim 13 but should be dependent on claim 14. Claim 15 will be examined as if it depends on claim 14.

Claim Rejections - 35 USC § 102

10. Claim 13 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Cragg et al., US 6,162,192. Cragg delivers the sponge pledget over a guidewire to ensure proper positioning, which anticipates the claimed “means for preventing the injected sponge material from entering an interior of the blood vessel.”

11. Claims 26 and 28 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Cragg et al., US 6,071,301. The claims hemostasis promoting delivery system is anticipated by

Cragg syringe 14, the connector is anticipated by Cragg Luer fitting 46. Note Cragg annular lip 32 (figure 2) which anticipates the claimed external flange of the introducer sheath.

Claim Rejections - 35 USC § 103

12. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hein, US 1,578,517. Hein bears a remarkable resemblance to the described subject matter, although it has a different use. See column 1, lines 10-13. Regarding the figures, see especially bleed back channel 10. See also MPEP 2111.02 and the case law therein. The examiner takes the position that the instant claims define a structurally complete invention in the body and the preamble phrase is not accorded much patentable weight. Accordingly, the only difference between Hein and the claimed invention is the recitation of the size of the bleed back element (less than 2 mm). However, it would be obvious to one of ordinary skill in the art to make the bleed back element any size necessary dependent upon patient need in the lack of a showing of criticality. See also MPEP 2144.04 IV.A. and the case law cited therein. It is well established that changes in size are prima facie obvious.

13. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw, US 5,431,639. See especially figure 3 and blood indicator 108. Accordingly, the only difference between Shaw and the claimed invention is the recitation of the size of the bleed back element (less than 2 mm). However, it would be obvious to one of ordinary skill in the art to make the bleed back element any size necessary dependent upon patient need in the lack of a

showing of criticality. See also MPEP 2144.04 IV.A. and the case law cited therein. It is well established that changes in size are prima facie obvious.

14. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg, US 6,071,301. The only difference between claim 27 and Cragg is that Cragg shows a connection for an external flange. It would be prima facie obvious to reverse the parts in the absence of a showing of criticality. All applicant claims is a different type of Luer system, which are notoriously old.

Allowable Subject Matter

15. Claims 1-12 are allowed.

16. Claims 14 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. Claim 15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

18. The following is a statement of reasons for the indication of allowable subject matter: Claims 1-12, 14, 15 and 19 are allowed/allowable (claims 5, 6 and 10 are rejoined) because the prior art does not disclose or reasonably suggest the control tip having a tube with an enlarged distal tip, in combination with the other elements as claimed. The closest prior art is the patent to

Cragg et al., US 6,162,192, which shows an introducer 12a having enlarged mid-section portions 64, but no enlarged distal end portions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is (703) 305-0154.

November 20, 2003


Sharon Kennedy
Primary Examiner